

08/ 962.027

9-25-08

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Docket No.: 20718/1204135-US3
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Letters Patent of:
Eugenio A. Cefali et al.

Patent No.: 6,818,229

Issued: November 16, 2004

For: INTERMEDIATE RELEASE NICOTINIC
ACID COMPOSITIONS FOR TREATING
HYPERLIPIDEMIA

Certificate
SEP 21 2006
of Correction

**REQUEST FOR CERTIFICATE OF CORRECTION
PURSUANT TO 37 CFR 1.323**

Attention: Certificate of Correction Branch
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

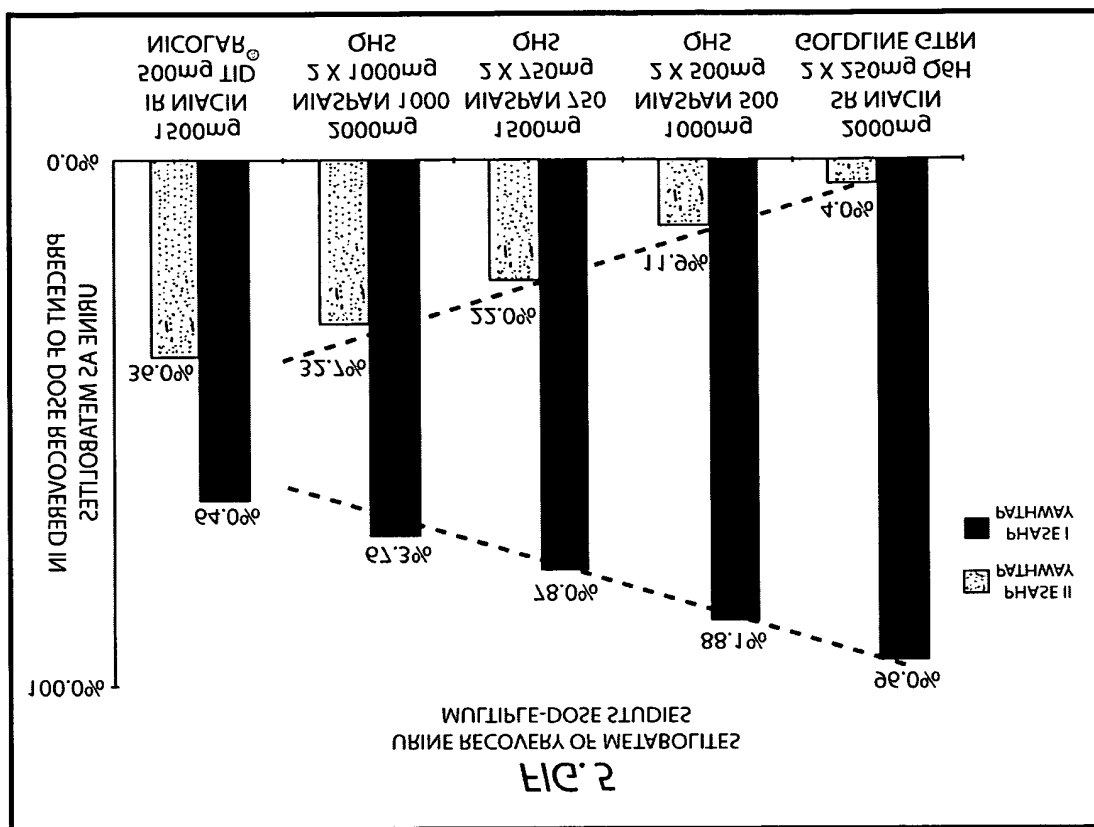
Upon reviewing the above-identified patent, Patentee noted typographical errors which should be corrected.

In the Specification:

At Figure Sheet 5 of 5, please replace Fig. 5 with the following corrected replacement figure:

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At column 2, line 67, please delete the phrase “18 or 78 percent” and insert the phrase --12 or 52 percent --.

At column 27, line 46, please delete the phrase “had 18 of 23, or 78 percent” and insert the phrase --had 12 of 23, or 52 percent--.

At column 27, please replace Table VIII with the following corrected replacement table:

TABLE VIII
A Comparison of Changes in Liver Function Tests

	DOSE							
	0	500	1000	1500	2000	2500	3000	TOTAL
McKenney SR^bNiacin								
AST	23.8	27.9	40.4	36.6	56.5	na	97.0	
%	--	117	170	154	237	na	408	
Invention Dosage^c								
AST	24.3	na	23.7	27.5	26.6	27.6	27.8	
%	--	na	98	113	109	114	114	
McKenney SR Niacin								
AST	25.6	29.5	36.3	39.0	59.1	na	100.0	
%	--	115	142	152	231	na	391	
Invention Dosage								
ALT	21.4	na	18.7	22.6	21.3	22.4	21.8	
%	--	na	87	106	100	105	102	
McKenney SR Niacin								
ALK	95	95	106	105	136	na	135	
%	--	100	112	111	143	na	142	
Invention Dosage								
ALK	74.7	na	73.9	76.1	73.4	76.7	78.0	
%	--	na	99	102	98	103	104	
McKenney SR Niacin								
Drop	--	0	1	2	4	na	5	12
n	--	--	--	--	--	--	--	23
%	--	0	4	9	17	na	22	52
Invention Dosage								
Drop	--	--	0	0	0	0	0	0
n	--	--	26	67	97	35	15	240
%	--	--	0	0	0	0	0	0
1 year	--	--	15	47	77	31	15	184
1 year	--	--	58	69	79	89	100	77

Dosed twice-per-day as described in "A Comparison of the Efficacy and Toxic Effects of Sustained - vs. Immediate - Release Niacin in Hypercholesterolemic Patients" by McKenney et al., *Journal of the American Medical Association*, March 2, 1994; Vol. 271, No. 9, pages 672-677.

^b SR is "sustained release"

^c Dosed once-per-day at night

Remarks:

The errors were found in the application as filed by applicant. The errors now sought to be corrected are inadvertent typographical errors, the correction of which does not involve new matter or require reexamination.

Our check in the amount of \$100.00 covering the fee set forth in 37 CFR 1.20(a) is enclosed. The Commissioner is authorized to charge any deficiency of up to \$300.00 or credit any excess in this fee to Deposit Account No. 04-0100.

Transmitted herewith is a proposed Certificate of Correction effecting such amendment. Patentee respectfully solicits the granting of the requested Certificate of Correction.

Dated: September 21, 2006

Respectfully submitted,

By: 

Paul M. Zagar, M.D.

Reg. No. 52,392

DARBY & DARBY P.C.

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New York, New York 10150-5257

(212) 527-7700 (Tel.)

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Attorneys/Agents For Applicant

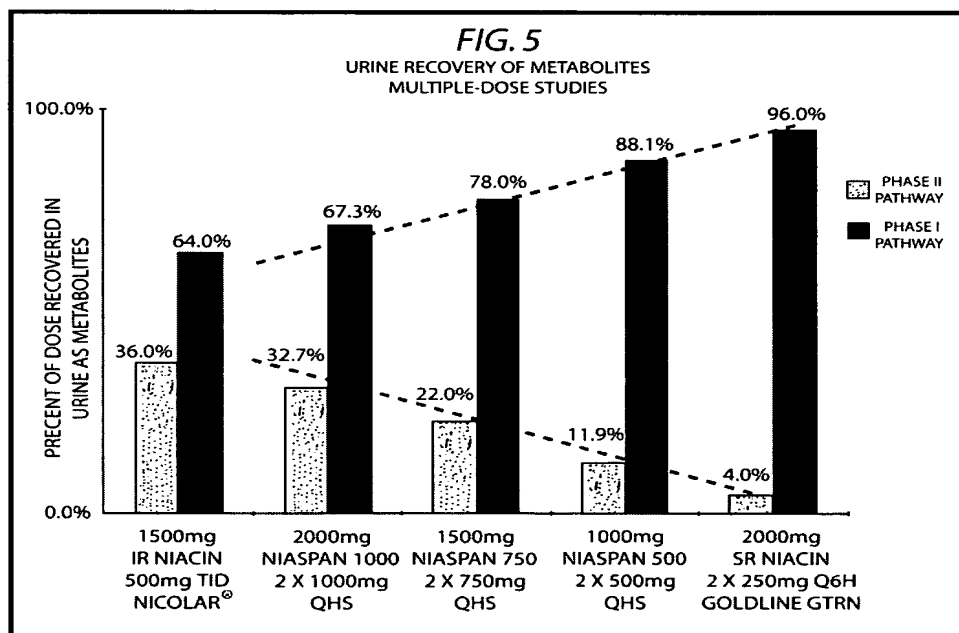
OCT - 2 2006

UNITED STATES PATENT AND TRADEMARK OFFICE CERTIFICATE OF CORRECTION

PATENT NO. : 6,818,229
APPLICATION NO. : 08/962,027
ISSUE DATE : November 16, 2004
INVENTOR(S) : Eugenio A. Cefali et al.

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

At Figure Sheet 5 of 5, please replace Fig. 5 with the following corrected replacement figure:



MAILING ADDRESS OF SENDER:
DARBY & DARBY P.C.
P.O. Box 5257
New York, New York 10150-5257 Page

Patent No.: 6,818,229

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Patent No.: 6,818,229

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Patent No.: 6,818,229



Application No. (if known): 08/962,027

Attorney Docket No.: 20718/1204135-US3

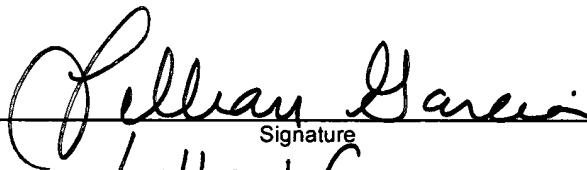
Certificate of Express Mailing Under 37 CFR 1.10

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Alexandria, VA 22313-1450

on September 21, 2006
Date



Signature

Lillian Garcia
Typed or printed name of person signing Certificate

Registration Number, if applicable

Telephone Number

Note: Each paper must have its own certificate of mailing, or this certificate must identify each submitted paper.

Fee Transmittal (1 page);
Request for Certificate of Correction (Fee Required) (4 pages);
Certificate of Correction (3 pages);
Check in the amount of \$100.00; and
Return Receipt Postcard.

OCT - 2 2006



Under the Paperwork Reduction Act of 1995, no person are required to respond to a collection of information unless it displays a valid OMB control number.

Effective on 12/08/2004. Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).		Complete if Known	
FEE TRANSMITTAL For FY 2005		Application Number	Patent#: 6,818,229
		Filing Date	Issued: November 16, 2004
		First Named Inventor	Eugenio A. Cefali
		Examiner Name	Robert M. Joynes
		Art Unit	N/A
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27	Attorney Docket No.	20718/1204135-US3	
TOTAL AMOUNT OF PAYMENT		(\$)	100.00

METHOD OF PAYMENT (check all that apply)

☒ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____

☐ Deposit Account Deposit Account Number: 04-0100 Deposit Account Name: Darby & Darby P.C.

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, **except for the filing fee**

☐ Charge any additional fee(s) or underpayment of fee(s) under 37 CFR 1.16 and 1.17 ☒ Credit any overpayments

FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid (\$)
	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description	Small Entity	
	Fee (\$)	Fee (\$)
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	200	100
Multiple dependent claims	360	180

Total Claims **Extra Claims** **Fee (\$)** **Fee Paid (\$)**

HP = highest number of total claims paid for, if greater than 20.

Indep. Claims **Extra Claims** **Fee (\$)** **Fee Paid (\$)**

HP = highest number of independent claims paid for, if greater than 3.

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee (\$)	Fee Paid (\$)
	- 100 =	/50	(round up to a whole number) x	=

4. OTHER FEE(S)

	Fees Paid (\$)
Non-English Specification, \$130 fee (no small entity discount)	
Other (e.g., late filing surcharge): <u>1811 Certificate of correction</u>	<u>100.00</u>

SUBMITTED BY			
Signature		Registration No. (Attorney/Agent)	52,392
Name (Print/Type)	Paul M. Zagar	Telephone	(212) 527-7700
		Date	September 21, 2006